K022989 1/2

510(k) Summary of Safety and Effectiveness

1. MANUFACTURER:

NOV 2 5 2002

Genzyme Biosurgery
A division of GENZYME CORORATION
600 Airport Road
Fall River, MA 02720

Contract: Karen K. Sylvia, Sr. Regulatory Specialist
Date Prepared: 6 September, 2002

2. DEVICE:

Tradename:	Tissue Retractor System
Classification:	Endoscopic Instruments and Accessories per 21 CFR § 876.1500)
Common Name:	Tissue Retractor

3. PREDICATE DEVICE:

The predicate devices used to determine substantial equivalence for the Genzyme Tissue Retractor System, are the SaphLITE® System marketed by Genzyme Biosurgery, Fall River, MA 02720 (K960400), and the ENDOPATH® Ultra-Retractor marketed by Ethicon Endo-Surgery, Inc. (K973139)

4. DEVICE DESCRIPTION:

The Genzyme Tissue Retractor System s is a surgical instrument that provides a means to create and maintain a cavity by retracting the subcutaneous layer to expose the conduit. The retraction is sufficient to allow enough exposure to dissect and retract subcutaneous tissue for performing all types of surgical procedures. This system consists of the following components:

- *Handle:* The handle securely holds the retractor blade, light panel, and provides a host adaptor for ACMI connection to a variety of commercially available light sources.

- *Retractor/blade:* The stainless steel retractor blade attaches to the handle for lifting the subcutaneous layer.

- *Fiber Optic Light Panel:* The light panel fits securely into the handle on the underside of the retractor blade to provide illumination for the procedure.

5. INTENDED USE:

The Tissue Retractor System is intended for use in dissecting and retracting in all types of surgical procedures requiring dissection and retraction of tissue.

6. COMPARISON OF CHARACTERISTICS:

The technological characteristics of the New Device are the same as the predicate devices.

The determination of substantial equivalence for this device was based on a detailed device description, conformance to consensus standards and voluntary standards.

Based on the 510(k) summaries and 510(k) statements (21 CFR §807 and the information provided herein, we conclude that the new device is substantially equivalent to the Predicate Devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 25 2002

Genzyme Biosurgery
Karen K. Sylvia
Senior Regulatory Specialist
600 Airport Road
Fall River, Massachusetts 02720

Re: K022989
Trade/Device Name: Tissue Retractor System
Regulation Number: 878.4580
Regulation Name: Surgical endoscopic light
Regulatory Class: Class II
Product Code: FSW
Dated: September 6, 2002
Received: September 9, 2002

Dear Ms. Sylvia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the

quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C Provzt

for Celia M. Witten, Ph.D., MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K022989

Device Name ***RadLite™ Tissue Retractor System***

Indications for Use

The RadLite™ Tissue Retractor System has application for the creation and maintenance of an operative cavity in the extraperitoneal spaces such as the retroperitoneal, preperitoneal and subcutaneous areas. The device may be used in all types of surgical procedures requiring retraction of tissue.

(Please do not write below this line - Continue on another page if necessary)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR § 801.109)

(Optional Format 1-2-96)

Miriam C Provost
(Division Sign-Off)
Division of Gen[illegible]rative
and Neurologica[illegible]ces

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